DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 13, 2015

Unimicro Medical Systems
% Mr. Long Yang
Shenzhen Hlongmed Biotech Company, Ltd.
R1508, East Building,Yihai Plaza, Chuangye Road, Nanshan District
Shenzhen, Guangdong 518054
People's Republic of China

Re: K142208
Trade/Device Name: Monopolar Laparoscopic Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 13, 2015
Received: February 23, 2015

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142208

Device Name
Monopolar Laparoscopic Accessories .Models ：Disposable Laparoscopic Scissors, Disposable Laparoscopic Forceps, Disposable Laparoscopic Electrodes

Indications for Use *(Describe)*
The Monopolar Laparoscopic Accessories is a family of instruments which includes forceps,scissors, and probes which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar electrosurgical cutting and/or coagulation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Unimicro Medical Systems (ShenZhen) Co., Ltd.

510(K) SUMMARY

This 510(k) summary is being submitted in accordance with 21 CFR §807.92.

Type of submission :Traditional

The assigned 510(K) number is: K142208

Prepared date: April9,2015

1. Submitter information:

Manufacturer Name: Unimicro Medical Systems (ShenZhen) Co.,Ltd.

Address: 2/F, Bldg 31, The 3rd Industrial Area, Mashantou, Gongming Street, Guangming New District, ShenZhen City,Guangdong Province, China

Tel : 0086-755-27111581

Fax : 0086-755-27111580

Establishment Registration Number:3010806467

2. Contact person:

Long Yang (COO)

Shenzhen Hlongmed Biotech Co., Ltd.

R1508, East Building, Yihai Plaza, Chuangye Road, Nanshan District,Shenzhen, P.R. China

Tel: 0086-755-86664986

Fax: 0086-755-86664933

E-mail: yanglong@hlongmed.com

3. Identification of the Device :

Trade Name: Monopolar Laparoscopic Accessories

Model: Disposable Laparoscopic Scissors

Disposable Laparoscopic Forceps

Disposable Laparoscopic Electrodes

Unimicro Medical Systems (ShenZhen) Co., Ltd.

Common Name: Electrosurgical, Cutting & Coagulation & Accessories

Classification Name: Electrosurgical, Cutting & Coagulation & Accessories

Regulation Number:878.4400

Device Classification: II

Product Code:GEI

4. Identification of the Predicative Device

Table 1: Predicative Device Information

Device Name	Common Name	Manufacturer	Classification and Code	Classification regulation	510(k) number
Unimax Laparoscopic Instrument	Electrosurgical, Cutting & Coagulation & Accessories	Unimax Medical Systems Inc.	Class II , GEI	21CFR 878.4400	K103508

5. Intended Use and Indications for Use of the subject device

The Monopolar Laparoscopic Accessories is a family of instruments which includes forceps,scissors, and probes which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar electrosurgical cutting and/or coagulation.

6. Device Description

The Monopolar Laparoscopic Accessories includes Grasping Forceps, Monopolar Scissors, and Monopolar Probe/Electrodes. The devices are disposable, single use, individually packaged devices that are composed of biocompatible materials. Scissors and forceps have a handle with rotating wheel attached to an insulated shaft with different

tips, which allows the shaft and tip to rotate. They include a male cautery connector when attached to standard monopolar cautery cables and their generators. Probes/Electrodes have an insulated shaft with a thermally conductive metal tip electrode. The proximal end of the shaft is attached to a handle made of an injection molded, medical grade plastic.

7. Non-clinical Testing

A series of in vitro and in vivo preclinical physical, mechanical and biocompatibility tests were performed to assess the safety and effectiveness of the Monopolar Laparoscopic Accessories.

The safety tests were conducted in accordance with IEC 60601-1 ,IEC 60601-1-2,IEC 60601-2-2, IEC 60601-2-18,10993-5,10993-7,10993-10,10993-11,10993-12,11135-1.

The performance testing was conducted including the items listed below:

- Drop Testing
- law Clamping Test
- Blade Sharpness Test
- Arcing Test
- Charring Test
- Thermal Spread Test

All the test results demonstrate the performance of Monopolar Laparoscopic Accessories meets the requirements of its pre-defined acceptance criteria and intended uses.

The results of the non-clinical testing demonstrate that the Monopolar Laparoscopic Accessories is as safe and effective as the predicate devices.

8. Safety and Effectiveness

The result of bench testing indicates that the new device is as safe and effective as the predicate device.

9. Substantial Equivalence Determination

The Monopolar Laparoscopic Accessories submitted in this 510(k) file is substantially

equivalent in intended use, design, principles of operation and performance to the cleared Unimax Laparoscopic Instrument which is the subject of K103508.

Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

The comparison to predicate device as below Table 2.

Table 2 : Comparison to Predicate Device

Item	**Proposed Device** Monopolar Laparoscopic Accessories	**Predicate Device** Unimax Laparoscopic Instrument(K103508)
Indications for Use	a family of instruments which includes forceps, scissors, and probes which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar electrosurgical cutting and/or coagulation.	a family of instruments which includes forceps, scissors, and probes which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar electrosurgical cutting and/or coagulation.
Consisted Instruments	● Standard insulated monopolar handles, ● Insulated Shafts, ● Class I inserts (forceps, scissors) ● Electrodes	● Standard insulated monopolar handles, ● Insulated Shafts, ● Class I inserts (forceps, scissors) ● Electrodes

Models	**Forceps:** Grasper Forceps Babcock Forceps Clinch Forceps Rat Tooth Forceps Dissector Forceps	**Grasping Forceps:** Straight grasping forceps Babcock grasping forceps Clinch grasping forceps Rat tooth grasping forceps Maryland dissecting forceps Duckbill grasping forceps Johan grasping forceps
	Scissors	**Scissors**
	Electrodes: Monopolar J hook probe Monopolar L hook probe Monopolar Spatula probe	**Electrodes:** Monopolar J hook probe Monopolar L hook probe Monopolar Spatula probe
Dimension	5mm/33cm	5mm/33cm 5mm/26cm 5mm/45cm
Safety standards	ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-11 ISO 10993-12 IEC 60601 -1 IEC 60601-2-2 IEC 60601-1-2 ISO 11135-1 IEC 60601-2-18	ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-11 ISO 10993-12 IEC 60601 -1 IEC 60601-2-2 IEC 60601-1-2 ISO 11135-1
Sterilization	EO	EO
Disposable	Yes	Yes
Compared performance testing	Drop Testing	Drop Testing
	Jaw Clamping Test	Jaw Clamping Test
	Blade Sharpness Test	Blade Sharpness Test

	Arcing Test Arcing Test	Arcing Test Arcing Test
	Charring Test	Charring Test
	Thermal Spread Test	Thermal Spread Test
	N/A	Bending Test
	N/A	Pulling Test
	N/A	Torque Test

10. Conclusion

After analyzing bench tests, safety testing data, it can be concluded that: Monopolar Laparoscopic Accessories is as safe and effective as the predicate device.